

ORIGINAL

AR201-13462



"Dongen, Ton van" <t.van.dongen@purac.com> on 01/04/2002 07:20:07 AM

To: NCIC OPPT/DC/USEPA/US@EPA
cc: "Vreeman, Gerrit" <g.vreeman@purac.com>, "Zoetemeyer, Rop" <r.j.zoetemeyer@purac.com>

Subject: Chemical right to know program; HPV files on lactic acid (#50-21- 5)

Dear administrator,

Herewith I submit, on behalf of PURAC America Inc., the proposed test plan together with the robust summary and the data on the SIDS endpoints for the chemical lactic acid, CAS number 50-21-5 (79-33-4). You will find all information in the ZIP file attached to this mail. The content of the ZIP file is given below. I understand that there will be a 120 days review period for the test plan. I trust that all comments received by the EPA will be forwarded to PURAC, for my attention.

It is good to mention that PURAC America Inc. was committed to send in data on CAS number 50-21-5, which is the racemic form of lactic acid. However, my company and most other suppliers of lactic acid, only manufacture the natural form of lactic acid, L(+) lactic acid. Most data available in public literature are about the L(+) form and most studies done have been performed with L(+) lactic acid. According to us, it made sense therefor to base the files on L(+) lactic acid (CAS# 79-33-4).

L(+) Lactic Acid is an organic acid, which is an essential element of human metabolism. Each human being metabolises between 125 and 150 grams of L(+) Lactic Acid daily. Therefor risk issues are not to be expected.

L(+) Lactic Acid has a GRAS status which can be found in 21 CFR § 184.1061. L(+) Lactic Acid is also included in the TSCA list.

L(+) Lactic Acid has been approved as a food additive (E 270), without restrictions under European legislation.

Please feel free to contact me (at telephone +31 183 695730 or e-mail t.van.dongen@purac.com) in case you have questions concerning this application.

I would appreciate if you would confirm the receipt of this mail.

Yours sincerely

Ton van Dongen
Corporate QA&RA Manager

RECEIVED
OPPT NCIC
02 JAN -6 PM 12:05

Encl. A zip file [HPV -50-21-5]

- Covering letter [letter right to know 50-21-5.doc]-
- Test pan justification and test plan [hpv_test plan justification & test plan 50-21-5.doc]
- MS-Word on L(+) Lactic Acid [HPV data 50_21_5.doc]

<<HPV 50-21-5.zip>>

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***** HPV 50-21-5.zip



201-13462

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Administrator
US Environmental Protection Agency
Attention: Chemical Right to Know Program
MERRIFIELD, VA 22116
USA

Gorinchem, January 4, 2002

Re : Chemical Right to Know Program

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The PURAC division
manufactures and
markets *natural* lactic
acid, lactates and lactitol.

Please feel free to contact me (at telephone +31 183 695730 or e-mail t.van.dongen@purac.com) in case you have questions concerning this application.

Yours sincerely

Ton van Dongen
Corporate QA&RA Manager

Encl. A zip file [HPV 79_33_4] with:

- This letter [letter right to know 50-21-5.doc]
- Robust summary and test plan [hvp_test plan justification & test plan 50-21-5.doc]
- MS-Word on L(+) Lactic Acid [HPV data 50_21_5.doc]